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1.0 Description of the Service

Allergies result from an overreaction of the immune system to foreign substances. While there are five classes of immunoglobulins, it is IgE that is typically involved in allergic reactions. Treatment options for allergies are avoidance of the allergen, pharmacological therapy, and immunotherapy.

1.1 Allergen Immunotherapy

Allergen immunotherapy, also known as desensitization, hyposensitization, allergy injection therapy, or “allergy shots,” consists of the **subcutaneous** administration of specific allergenic extracts as antigens to individuals with IgE-mediated conditions. In the build-up phase, injections are given at periodic intervals, usually on an increasing dosage scale as immunity to the antigen develops. In the maintenance phase, injections are given at three- to four-week intervals, the regimen determined by patient tolerance and relief of symptoms.

1.2 Rapid Desensitization

Rapid desensitization (also called rush immunotherapy or cluster immunotherapy) applies to clinical situations in which multiple injections of antigens are administered over a few hours at 30- to 120-minute intervals to rapidly neutralize available IgE antibodies.

1.3 Preparation and Administration Services

Allergen immunotherapy is comprised of two services: preparation of the supply of antigen and the administration of the antigen.

Note: Medicaid **does not cover** the complete service code, which describes the combined supply of antigen and allergy injection provided during a single encounter, as described in **Section 4.3**.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the

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best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, Sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/medbillcaguide.htm>

EPSDT provider page: <http://www.ncdhhs.gov/dma/EPsDTprovider.htm>

3.0 When the Procedure Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

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3.1 General Criteria

Medicaid covers allergen immunotherapy when it is medically necessary and

- a. the procedure is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Allergen immunotherapy is considered medically necessary when **all of the following** criteria apply:

- a. The hypersensitivity cannot be managed by medications or allergen avoidance.
- b. Skin testing or blood tests must have determined the presence of allergies, as described in Clinical Coverage Policy 1N-1, Allergy Testing.
- c. The recipient selected for immunotherapy must have clinically significant allergic symptoms or a chronic allergic state caused by **any** of the following:
 1. stinging insect hypersensitivity
 2. inhalant allergies
 3. allergic asthma
 4. allergic rhinitis or conjunctivitis
 5. dust mite atopic dermatitis

3.3 Rapid Desensitization

Rapid desensitization is considered medically necessary for either:

- a. insect sting hypersensitivity (Hymenoptera—e.g., wasps, hornets, bees, fire ants),
or
- b. IgE antibodies to a medically necessary drug for which substitution with an alternative medicine is not an effective option
or
- c. moderate to severe allergic rhinitis who need treatment during or immediately before the season of the affecting allergy.

4.0 When the Procedure Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

4.1 General Criteria

Allergen immunotherapy is not covered when:

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure unnecessarily duplicates another provider's procedure; or
- d. the procedure is experimental, investigational, or part of a clinical trial.

4.2 Specific Exclusions

- a. Allergen immunotherapy will not be covered for non-allergic asthma or for the following antigens:
 1. food allergies
 2. newsprint
 3. tobacco smoke
 4. dandelion
 5. orris root
 6. phenol
 7. formalin
 8. alcohol
 9. sugar
 10. yeast
 11. grain mill dust
 12. pyrethrum
 13. marigold
 14. soybean dust
 15. honeysuckle
 16. wool
 17. fiberglass
 18. green tea
 19. chalk
- b. Allergen proof supplies, such as mattresses, mattress casings, pillows, pillow casings and other supplies that are commonly used in the management of allergy patients, are not covered. These supplies can be used for non-medical purposes and may be considered personal convenience items. They are not considered medically necessary for the treatment of illness.

Note: These lists are not all inclusive.

4.3 Excluded CPT Codes

Medicaid does not cover CPT codes 95120 through 95134, which describe the complete service code for the combined supply of antigen and allergy injection provided during a single encounter.

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Note: The supply (preparation) of antigen(s) and the administration of the antigen(s) **must be billed separately**, using two different CPT codes.

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

5.1 Prior Approval

Prior approval is not required.

5.2 Office Visits

An office visit cannot be billed in conjunction with an allergy injection unless the office visit represents another significant separately identifiable service.

Note: Providers must append Modifier 25 to the office visit procedure code to indicate that a separately identifiable service was provided.

5.3 Definition of Units

Providers must bill for services using the unit of billing defined for use by Medicaid.

5.3.1 Administration of Antigen(s) by Injection

For 95115, one unit is billed when only one injection is given on the same day.

For 95117, one unit is billed when two or more injections are given on the same day of service.

5.3.2 Allergy Treatments

For 95180, rapid desensitization must be billed **as one hour equals one unit**.

5.3.3 Preparation of Antigen(s)

A billing unit describes 0.5 cubic centimeter (cc) of solution from a multi-dose vial. Providers must bill **0.5 cubic centimeter equals one unit**. This applies to venom and non-venom antigen codes.

The supply (preparation) of antigen(s) and the administration of the antigen(s) **must be billed separately**, using two different CPT codes.

5.4 Duration of Treatment

As indicated in **Section 3.1**, allergen immunotherapy must be individualized, specific, and consistent with the recipient's symptoms or confirmed diagnosis. However, treatment beyond a two year period is not covered when:

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- a. the recipient does not experience a noticeable decrease of symptoms,
- b. the recipient does not demonstrate an increase in tolerance to the offending allergen,
- c. there is not a reduction in medication usage.
- d. there is no documented clinical benefit.

6.0 Providers Eligible to Bill for the Procedure

Providers who meet Medicaid's qualifications for participation and are currently enrolled with the N.C. Medicaid program are eligible to bill for allergen immunotherapy when the procedure is within the scope of their practice.

7.0 Additional Requirements

7.1 Medical Records

7.1.1 Records Retention

As a condition of participation, providers are required to keep records necessary to disclose the extent of services rendered to recipients and billed to the N.C. Medicaid program [Social Security Act 1902(a)(27) and 42 CFR 431.107]. Records must be retained for a period of not less than five years from the date of service, unless a longer retention period is required by applicable federal or state law, regulations, or agreements (10A NCAC 22F.0107).

Copies of records must be furnished upon request.

The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit the release of records to Medicaid (45 CFR 164.502).

7.1.2 Documentation

Medical record documentation must:

- a. confirm that allergen immunotherapy is medically necessary and clinically reasonable,
- b. demonstrate that indications for immunotherapy were determined by appropriate diagnostic procedures,
- c. include reactions to injections, if any
- d. include continuing evaluation of the effectiveness of treatment
- e. reflect the number of vials and doses prepared and the injection schedule.

7.2 Federal and State Requirements

All providers must comply with all applicable federal and state regulations and laws.

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8.0 Policy Implementation/Revision Information

Original Effective Date:

Revision Information:

Date	Section Revised	Change

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Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Codes

1. Administration of antigen(s) by injection

CPT Code	Description of Service
95115	Professional services for allergen immunotherapy not including the provision of allergenic extracts, single injection
95117	Professional services for allergen immunotherapy not including the provision of allergenic extracts, two or more injections

2. Allergy treatments

CPT Code	Description of Service
95180	Rapid desensitization procedure, each hour (eg, insulin, penicillin, equine serum)

3. Preparation of antigen(s)

CPT Code	Description of Service
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials)
95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom
95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); two single stinging insect venoms
95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); three single stinging insect venoms
95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); four single stinging insect venoms
95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); five single stinging insect venoms

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CPT Code	Description of Service
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
95170	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses); whole body extract of biting insect or other arthropod

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The supply (preparation) of antigen(s) and the administration of the antigen(s) **must be billed separately**, using two different CPT codes.

1. Administration of Antigen(s) by Injection

For 95115, one unit is billed when only one injection is given on the same day.

For 95117, one unit is billed when two or more injections are given on the same day of service.

2. Allergy Treatments

For 95180, rapid desensitization must be billed **as one hour equals one unit**.

3. Preparation of Antigen(s)

A billing unit describes 0.5 cubic centimeter (cc) of solution from a multi-dose vial. Providers must bill **0.5 cubic centimeter equals one unit**. This applies to venom and non-venom antigen codes.

F. Place of Service

Outpatient and office settings.

G. Co-payments

Allergen Immunotherapy services are subject to co-payment requirements.

H. Reimbursement

Providers must bill their usual and customary charges.